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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,738	11/20/2003	Hiroyuki Odaka	2596 USIP	8700

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TAKEDA PHARMACEUTICALS NORTH AMERICA, INC  
INTELLECTUAL PROPERTY DEPARTMENT  
475 HALF DAY ROAD  
SUITE 500  
LINCOLNSHIRE, IL 60069

EXAMINER

WEDDINGTON, KEVIN E

ART UNIT PAPER NUMBER

1614

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/717,738

Applicant(s)

ODAKA ET AL.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-12, 16, 18 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-12, 16, 18 and 23-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/937,447.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11-20-03</u> . | 6) <input type="checkbox"/> Other: _____  |

Claims 9-16, 18 and 23-30 are presented for examination.

Applicants' preliminary amendment and information disclosure statement filed November 20, 2003 have been received and entered.

*Priority*

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).  
The certified copy has been filed in parent Application No. 09/937,447, filed on February 26, 2001.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' specification does not contain any test results or experimental data showing the instant sensitizers will, in fact, prevent disturbance of consciousness, coma or respiratory diseases in a mammal not presently at risk of or predisposed to developing such conditions.

Claim 12 is not allowed.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pioglitazone; compounds of the formula II; 5-[[6-(2-fluorobenzyloxy)-2-naphthyl]methyl]-2,4-thiazolidinedione; FK-614; and KRP-297, does not reasonably provide enablement for other insulin sensitizers, such as metformin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

It is not pointed out how the applicants can improve acidosis caused by a biguanide (as stated in the enclosed Sirtori et al. reference) with an insulin sensitizer, namely metformin (a biguanide).

Claim 18 is not allowed.

To overcome this rejection, applicants may wish to amend claim 18 by inserting the limitations of claims 28-30 to exclude metformin.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

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to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-12, 18 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kemnitz et al. (PTO-1449), Momose et al. (6,251,926) and Acton III, et al. (2002/0042441).

Kemnitz et al. teach an insulin sensitizer, pioglitazone, for increasing insulin sensitivity, reduces blood glucose, insulin and lipid levels in mammals.

Momose et al. teach oxyminoalkanoic acid derivatives derived from formula I (see claim I of the reference). Note the cited reference formula I is the same as applicants' formula II disclosed in claim 28 and 29. Note the instant oxyminoalkanoic acid derivatives are used to treat diabetes and complication associated with diabetes.

Acton III, et al. teaches PPAR gamma dual agonist, such as KPR-297, is well-known to treat diabetes and other diabetic complication associated with diabetes.

The instant invention differs from the cited reference in that the cited reference does not teach the preferred insulin sensitizers are used to improve and treat acidosis. However, one skilled in the art would have been motivated to treat improve or treat acidosis since acidosis is considered to be one complication associated with diabetes in the absence of evidence to the contrary.

For the method of improving acidosis in a mammal with the instant insulin sensitizers are not persuasive since the instant insulin sensitizers are well-known in the art to treat all complications associated with diabetes including ketosis.

Claims 9-12, 18 and 28-30 are not allowed.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kemnitz et al. (PTO-I449), Inoue et al. (PTO-I449) or Fujiwara (PTO-I449) in view of Windholz et al. (PTO-I449).

Kemnitz et al., Inoue et al., or Fujiwara teach individually insulin sensitizers that are used to treat diabetes and complications associated with diabetes.


The instant invention differs from the cited references in that the cited references do not teach the addition of insulin with the insulin sensitizers. However, the secondary reference, Windholz et al., disclose insulin as a well-known compound used to treat diabetes and complication associated with diabetes. Clearly, the combination of the two compounds into a single composition would give an additive effect in the absence of evidence to the contrary.

Claims 16 and 23-27 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571) 272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington  
July 6, 2004